

## **DETAILED ACTION**

### ***Application Status***

1. Applicant's response filed to the Office Action mailed December 31, 2009 on February 26, 2010, is acknowledged.

### ***Claim Disposition***

2. Claims 1-2, 4-13, 17-18 and 20 are pending and are under examination.

### ***Claim Objection***

3. Claim 1 is objected to because of the following informalities:

For clarity and precision of claim language it is suggested that claim 1 is amended to read:

"A method of treating an inflammatory disorder, wherein the inflammatory disorder is mediated by free radical damage in a patient in need thereof comprising: [[, the method comprising]]  
administering to said patient a pharmaceutical composition comprising a pharmaceutically acceptable carrier, wherein said composition comprises heme oxygenase-1 (HO-1), bilirubin, biliverdin, ferritin, iron, desferoxamine, salicylaldehyde isonicotinoyl hydrazone, iron dextran, or apoferritin in an amount sufficient to treat the inflammatory disorder; and wherein the inflammatory disorder is localized in the

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gastrointestinal tract”.

Correction is required.

### ***Claim Rejections - 35 USC 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

4. Claims 1-2, 4-13, 17-18 and 20 are rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter, which applicant (s) regard as their invention.

Claim 1 and the dependent claims hereto are confusing thus indefinite for the recitation of "comprising, the method comprising". In addition, the claim is directed to a method of treating an inflammatory disorder in a patient, however, the it is unclear as to whether said patient is in need of such a treatment.

### ***Response to Arguments***

5. Applicant's remarks have been considered in full. Note that the rejections of record are withdrawn, thus applicant's comments are moot and will not be addressed herein. Note however, that new grounds of rejections have been instituted under 35

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USC 112, second paragraph for the reasons set forth above based on amendments made to the claims.

### ***Conclusion***

6. No claims are presently allowable.

7. Applicant's amendment necessitated the new/modified ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HOPE A. ROBINSON whose telephone number is (571)272-0957. The examiner can normally be reached on Monday-Friday 9:00-6:30 from 10:00 a.m. to 6:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, can be reached at (571) 272-0811.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/Hope A. Robinson/

Primary Examiner, Art Unit 1652